

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S Appln. No: 10/031,409

REMARKS

The Examiner has not indicated that the drawing filed on January 18, 2002 has been accepted. Applicants respectfully request that the Examiner make such an acknowledgment.

In the Form PTO-1449 (enclosed herewith) filed with Applicants' Information Disclosure Statement of April 19, 2002, under Foreign Patent Documents, the Examiner crossed out JU 3-066506. The Examiner did not provide any explanation. The Examiner is kindly directed to the paragraph bridging pages 1 and 2 of the present specification, for the discussion of relevance of JU 3-066506. Applicants respectfully request that the Examiner initial the Form PTO-1449 indicating that JU 3-066506 has been considered.

In this Amendment, claims 4-7 and 10-11 have been amended to be in proper dependent form.

Claims 6 and 8 have been amended to delete the language "with a part of the applicator" for clarification purposes. Such an amendment should not be deemed to narrow the scope of the invention.

The specification has been amended to correct an error caused by a signal distortion. Specifically, at page 8, line 16, the Specification has been amended to replace "?-ray" with --gamma-ray--. Applicants have also attached herewith a copy of the corresponding page of the PCT application which clearly shows "γ-ray" (gamma-ray) instead of "?-ray."

No new matter has been added and thus, entry of the Amendment is respectfully requested. Upon entry of the Amendment, claims 1-12 are all of the claims pending in the application.

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S Appln. No: 10/031,409

At page 2 of the Office Action, claims 8-12 have been rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite.

In particular, it was asserted (1) that the term “applicator” was not clearly defined, (2) that the phrase “to adhere to skin with a part of the applicator” in claim 8, lines 10-11 was unclear as to what Applicants are intending to claim, and (3) that the language “the sticky agent layer was used as the ointment applicator” in Example 5 at page 19, lines 8-9, was unclear.

Applicants respectfully traverse the rejection regarding the term “applicator” and the language “the sticky agent layer was used as the ointment applicator.”

Applicants also respectfully submit that claim 8 as amended is not indefinite. In this Amendment, claim 8 has been amended to delete the language “with a part of the applicator.”

Regarding the term “applicator,” it is sufficiently described in the specification. For example, at page 3, lines 1-4 and page 13, lines 1-2, an ointment applicator is described to include “a support and an adhesive layer disposed on one surface of the support” wherein the “support is not pre-coated with the ointment.”

Regarding the language “the sticky agent layer was used as the ointment applicator” in Example 5, the Examiner might have misread the sentence. Example 5 describes an ointment applicator wherein a support with a sticky agent layer, but not the sticky agent layer itself, was used.

In view of the above, the Examiner is respectfully requested to reconsider and withdraw the rejection.

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S Appln. No: 10/031,409

At page 3 of the Office Action, claims 1 and 6 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Ueda et al (U.S. Patent No. 5,045,553).

Ueda et al was relied upon to teach a pharmaceutical composition in a patch preparation comprising a support and a gel (ointment), wherein the gel is coated over the aluminum support in an amount of 38.3 mg/cm² and the thickness of the ethylene vinyl acetate support film is 50 microns (column 7, lines 15-20 - Example 12). Ueda et al was also relied upon to teach that the gel patch preparation can further include an acrylic adhesive layer on the film (column 7, lines 15-45).

Applicants respectfully traverse the rejection because Ueda et al does not teach or suggest the present invention.

Example 12 of Ueda et al describes a patch preparation produced by spreading a solution gel over an aluminum support in an amount of 38.3 mg/cm² and sealing the gel with an EVA film, wherein the EVA film has a thickness of 50μm (column 7, lines 15-20). Ueda et al also discloses that a support member can be made of cloth or aluminum (column 3, line 48).

Accordingly, in Example 12 of Ueda et al, the support member is aluminum and the EVA film is an absorption promoter release-controlling film (column 4, lines 10-18 and Fig.4).

However, Ueda et al does not disclose or suggest the characteristics of the support member as presently claimed, i.e., thickness of 1-2000μm and 50% modulus of 5-600g/cm. Applicants respectfully submit that cloth and aluminum do not inherently possess these properties.

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S Appln. No: 10/031,409

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection.

At page 4 of the Office Action, claims 1-12 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ueda et al.

In particular, Ueda et al was relied upon to teach, in addition to that described above, that the pharmaceutical composition can be administered in various dosage forms: tapes (column 3, lines 43-55), ointment (column 3, lines 64-68), in a container (column 4, line 4) and patches (column 4, lines 10-20).

The Examiner asserted that it would have been obvious to one of ordinary skill in the art to determine suitable amounts or ranges of water vapor permeability through routine or manipulative experimentation.

Applicants respectfully traverse the rejection because the Examiner has not established a *prima facie* case of obviousness over Ueda et al.

Ueda et al does not disclose a support member of specific characteristics as presently claimed (i.e., thickness, 50% modulus and water vapor permeability). There is no indication in Ueda et al that use of a support with these specific properties would improve percutaneous absorption of an active ingredient, which was the main objective of Ueda et al.

In fact, all of the Examples in Ueda et al describe a support member made of aluminum, which does not possess the presently claimed thickness or water vapor permeability properties.

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S Appln. No: 10/031,409

Further, Ueda et al discloses the percutaneous composition comprising a specific active ingredient, wherein the composition is spread over the aluminum support. Ueda et al mentions that by the aluminum support, adherence of ointment to clothes can be prevented.

On the other hand, the ointment patch of the present invention can prevent transfer of ointment elsewhere as well as reduction in its drug releasing ability, without causing discomfortableness when applied to skin.

Applicants have conducted extensive studies to obtain the ointment applicator having the above underlined quality and arrived at the present invention. Since Ueda et al is silent on the above underlined quality, it does not render *prima facie* obvious the present invention.

Mr. Susumu Maruo, a co-inventor of the present invention has made the following statements.

Generally speaking, ointment has expansibility and can be applied to body areas, such as joint areas, i.e., elbows or knees. However, there is a problem in that ointment can be transferred elsewhere.

To solve the problem of the transfer of ointment, Ueda et al provides a gel composition with an aluminum support. However, the gel composition with an aluminum support tends to come off if the gel composition is applied to body areas such as joint areas. Further, another problem, i.e., skin irritation etc., occurs when the composition has sufficient adhesion to which prevent it from peeling off of the skin. Additionally, the composition with a water resistant support, such as aluminum, causes a big change the in the percutaneous drug absorption ratio. Such a big change could result in serious side effects due to the sealing effect of the support.

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S Appln. No: 10/031,409

In contrast, the present invention provides an ointment patch on a support having a specific thickness and a 50% modulus. The present invention solved the problems encountered in Ueda et al, such as coming off when applied to joint areas, skin irritation and side effects.

In view of the above, the present invention is not rendered *prima facie* obvious by Ueda et al, and therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Fang Liu
Registration No. 51,283

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE



23373

PATENT TRADEMARK OFFICE

Date: April 24, 2003